

TEHNOMEDICA

str.Ciuflea, 38/1 MD-2001, mun. Chișinău, Moldova tel./fax: (022)601 102, 601 087
e-mail <tehnomedica_md@yahoo.com> <tehnomedicamd@gmail.com>

Anexa nr. 8
la Documentația standard nr.115
din 15.09.2021

DECLARAȚIE privind valabilitatea ofertei

Către IMSP Institutul de Medicină Urgentă

Stimați domni,

Ne angajăm să menținem oferta valabilă, privind achiziționarea seturilor jetabile pentru operații neurochirurgicale – 2023, prin procedura de achiziție valoare mică, pentru o durată de 60 zile (șaizeci zile), respectiv până la data de 14.08.2023 (ziua/luna/anul), și ea va rămâne obligatorie pentru noi și poate fi acceptată oricând înainte de expirarea perioadei de valabilitate.

Data completării: 10.06.2023

Cu stimă,

Tehnomedica SRL

Director Tatiana Roibu

(semnătura autorizată)



I.P. "AGENȚIA SERVICII PUBLICE"

Departamentul înregistrare și licențiere a unităților de drept

EXTRAS

din Registrul de stat al persoanelor juridice

nr. 1968 din 01.02.2019

Denumirea completă: **SOCIETATEA CU RĂSPUNDERE LIMITATĂ
«TEHNOMEDICA» .**

Denumirea prescurtată: **«TEHNOMEDICA» S.R.L. .**

Forma juridică de organizare: **Societate cu Răspundere Limitată.**

Numărul de identificare de stat și codul fiscal: **1002600053256.**

Data înregistrării de stat: **17.04.2002.**

Sediul: **MD-2001, str. Ciuflea, 38/1, mun.Chișinău, Republica Moldova.**

Obiectul principal de activitate:

- 1 Fabricarea utilajului medical și chirurgical și a dispozitivelor ortopedice;**
- 2 Comerțul cu ridicata al produselor farmaceutice;**
- 3 Comerțul cu amănuntul al produselor farmaceutice;**
- 4 Practica medicală;**
- 5 Importul, fabricarea, comercializarea, asistența tehnică și (sau) reparația dispozitivelor medicale și (sau) a opticii;**
- 6 Activități de consultare pentru afaceri și management.**

Capitalul social: **5400 lei.**

Administrator: ROIBU TATIANA,

Asociați:

- 1. ROIBU TATIANA 100 %.**

Prezentul extras este eliberat în temeiul art. 34 al Legii nr. 220-XVI din 19 octombrie 2007 privind înregistrarea de stat a persoanelor juridice și a întreprinzătorilor individuali și confirmă datele din Registrul de stat la data de: 01.02.2019.

Specialist coordonator
tel. 022-20-7838



Clichici Elena



EB 0257484

Nr. CIF26-842.2020
Data: 13 Februarie 2020

**CERTIFICAT
PRIVIND EXISTENTA CONTURILOR CURENTE**

Prin prezentul, **Mobiasbanca - OTP Group S.A.**, codul băncii (BIC): **MOBBMD22**, confirmă că compania **TEHNOMEDICA S.R.L.** cod fiscal (IDNO) **1002600053256**, detine următoarele conturi curente la Mobiasbanca - OTP Group S.A., Sucursala. 26 Negruzzi:

1. **MDL - MD65MO2224ASV98310887100**
2. **EUR - MD06MO2224ASV98311097100**


L.S.
Numele, Prenumele si Semnatura
Director sucursalei „Gheorghe Mocanu”



Executor :Eduard Cilcic
Tel: 022-812-150

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Către IMSP Institutul de Medicină Urgentă

În atenția Grupului de lucru
al procedurii nr. ocds-b3wdp1-MD-1686128817078,
ID:21081985

Declarație privind disponibilitatea prezentării mostrelor

Prin prezenta, declarăm că vom prezenta mostre în decurs de 3 zile de la solicitarea autorității contractante pentru produsele oferite în cadrul procedurii preonate privind achiziționarea seturilor jetabile pentru operații neurochirurgicale – 2023.

Cu respect,

Director

Tatiana Roibu

TEHNOMEDICA

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e-mail <tehnomedica_md@yahoo.com> <tehnomedicamd@gmail.com>

Către IMSP Institutul de Medicină Urgentă

În atenția Grupului de lucru
al procedurii nr. ocds-b3wdp1-MD-1686128817078,
ID:21081985

DECLARAȚIE

**privind înregistrarea în Registrul de Stat al Dispozitivelor Medicale al Agenției
Medicamentului și Dispozitivelor Medicale**

Prin prezenta, declarăm că produsele oferite în cadrul licitației deschise prenotate sunt înregistrate în Registrul de Stat al Dispozitivelor Medicale a Agenției Medicamentului și Dispozitivelor Medicale.

Dovada înregistrării dispozitivelor medicale se regăsește pe pagina web a Agenției Medicamentului și Dispozitivelor Medicale www.amdm.gov.md.

DM000374810	NEUROSURGICAL TRAYS	97094658	Suedia	MÖLNLYCKE HEALTH CARE AB	TEHNOMEDICA S.R.L.	Rg04-000229	27-09-2022
DM000374811	NEUROSURGICAL TRAYS	97095457	Suedia	MÖLNLYCKE HEALTH CARE AB	TEHNOMEDICA S.R.L.	Rg04-000229	27-09-2022

Cu respect,

Director

Tatiana Roibu

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Mölnlycke Health Care AB
Gamlestadsvägen 3C
Box 13080
SE-402 52 Göteborg
Sweden

Holds Certificate Number:

MD 83345

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

The design, development, manufacture, marketing, sales and distribution of sterile wound and scar dressings, open wound products, cavity dressings, polyurethane foam with and without additives for incorporation into medical devices, swabs, sponges, sterile alcohol wipes, skin care products, non-sterile textile bandages and support, sterile wound irrigation solutions, operation sets, surgical and equipment drapes, procedure packs, surgical gowns and medical staff clothing for use in the patient environment, sterile and non-sterile medical gloves and sterile surgical gloves, self-warming blankets, turning and positioning devices. The design, development, manufacture, marketing, sales and distribution of single patient use Negative Pressure wound therapy pumps and accessories. Distribution of laparoscopic instruments.



For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2004-07-21

Latest Revision Date: 2021-11-24

Effective Date: 2021-11-28

Expiry Date: 2024-11-27

Page: 1 of 1



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EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

No.**CE 01966****Issued To:**

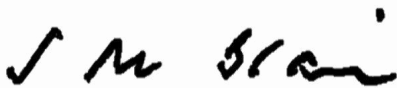
**Mölnlycke Health Care AB
Box 13080
Gamlestadsvägen 3C
SE-402 52 Göteborg
Sweden**

In respect of:

See certificate scope page.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex V. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb and class III products an Annex III certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):



Stewart Brain, Head of Compliance & Risk -
Medical Devices

First Issued: **1998-06-29**

Date: **2018-05-30**

Expiry Date: **2023-06-28**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

Certificate No: CE 01966

Certificate Scope:

Those aspects of manufacture related to securing and maintaining sterility of absorbent tracheostomy dressing, sterile scar management dressing and transparent adhesive IV film dressing.

Those aspects of manufacture related to securing and maintaining sterility of negative pressure wound therapy (NPWT) accessories, surgical and equipment drapes and surgical gowns.

Those aspects of manufacturing relating to securing and maintaining sterility in the assembly of procedure packs in accordance with article 12 of the MDD.

First Issued: **1998-06-29**Date: **2018-05-30**Expiry Date: **2023-06-28**

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Page 2 of 2

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

We, Mölnlycke Health Care AB, Gamlestadsvägen 3C, Box 13080, SE-402 52 Göteborg, Sweden being the assembler of the following declare that the procedure packs listed in the attached schedule are in conformity with the provisions of Article 12 in the Council Directive 93/42/EEC of 14 June 1993, as amended by 2007/47/EEC, concerning medical devices, the Medical Devices Act SFS 1993:584 and the Swedish Medical Product Agency regulations and guidelines: Medical Devices, LVFS 2003:11, as amended by LVFS 2009:18.

Trade Name: *Mölnlycke® Procedure Trays*

The mutual compatibility of each device within the Mölnlycke Health Care procedure packs has been verified in accordance with the relevant instructions for use provided by the manufacturer of each device and / or the approved indications for use of each device.

Where appropriate, the relevant instructions for use are provided.

Procedure packs are assembled in accordance with a documented quality management system and therefore, subject to internal controls and inspection prior to release that ensures the safety, quality and performance of the procedure pack.

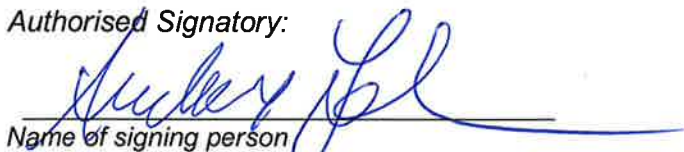
Sterilisation after assembly:	<i>EtO, Ethylene Oxide</i>
CE certificate	<i>CE 01966</i>
Certificate issued by	<i>BSi (0086)</i>

For sterilised procedure packs, the sterilisation process is performed in accordance with the manufacturer(s)' instructions and follows the procedures of Annex V of 93/42/EEC.

For systems and procedure packs, the intervention of the notified body is limited to the aspects of the procedure relating to the obtaining of sterility.

Signed for and on behalf of Mölnlycke Health Care

Authorised Signatory:



Name of signing person

RA Manager, Medical Devices

This document has been printed by the PRIME system. The validity of this document cannot be guaranteed.

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Product reference	Product Name	Product Description / included devices	GMDN code
See products linked to this document in the ERP system.			

Product name, article number, manufacturer and notified body number for each device included in the system or procedure pack can be found in the BOM in the ERP system.

Signed for and on behalf of Mölnlycke Health Care

Authorised Signatory:



Name of signing person

RA Manager, Medical Devices



Tray ID 97095457
 Tray name SET CHIRURGICAL ABORD CEREBRAL
 Speciality filter NEUROSURGERY
 Intervention filter Craniotomy
 Hospital filter Tehnomedica SRL

Description		Qty
	Crepe paper 60x60cm 60g/m2 White	1
	BNS Craniotomy Drape 230x300cm Inc. 30x20	1
	Adh. op towel 50x50cm	4
	Hand towel 18x25cm	2
	Op tape 9x49cm	1
	Suction And Diathermy Bag, 40x35 cm	1
	Neuro swab gauze 12,7x38,1mm	10
	Microscope Drape Zeiss 117 x 267cm	1



Forceps Bipolar Bayonet

1



Medicine/Specimen cup 120ml Polyethylene

1



Scalpel blade CS N°22

1



Plastic bag 20x30cm Ziplock Transp.

1



Instrument cleaner 5x5cm

1



Scalpel blade CS N°15

1



Syringe 20ml L/L 3parts Conc.

3



Light handle cover large Light green/white collar

2



Suction Catheter 12Ch 50cm 2eyes Funnel str PVC Shore 70

1



Mayo stand cover 79x145cm Abs.65x85cm

2



Surg.glove latex 8.0 PF 2/1

2



Surg.glove latex 8.5 PF 2/1

1



Skin marker taper tip Violet

1



Reinforced Table Cover 190 x280 wrapping

1

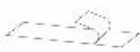
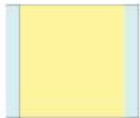


SA Label 1,6 x 5cm Red TEHNOMEDICA SRL

1



Tray ID 97094658
 Tray name SET CHIRURGICAL ABORD SPINAL
 Colour code
 Speciality filter NEUROSURGERY
 Intervention filter Laminectomy/Spinal
 Hospital filter Tehnomedica SRL (245686)

Description		Qty
	Adh. op sheet 240x150cm	1
	Op tape 9x49cm	1
	Adh. op sheet 175x175cm	1
	Incise drape 30x26cm Inc.30x20cm	1
	Suction And Diathermy Bag, 40x35 cm	2
	Crepe paper 60x60cm 60g/m2 White	1
	Adhesive op towel 90x75cm Reinf.	2



Hand towel 18x25cm

4



Neuro swab gauze 12,7x38,1mm

10



Medicine/Specimen cup 120ml Polyethylene Transp. Lid

1



Banded bag 140cm Circ. Elast. Transp.

1



Microscope Drape Zeiss 117 x 267cm

1



Scalpel blade CS N°11

1



Forceps Bipolar Straight 200mm

1



Scalpel blade CS N°22

1



Plastic bag 20x30cm Ziplock Transp.

1



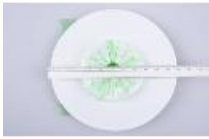
Instrument cleaner 5x5cm

1



Syringe 20ml L/L 3parts Conc.

3



Light handle cover large Light green/white collar

2



Suction Catheter 12Ch 50cm 2eyes Funnel str PVC Shore 70

1



Mayo stand cover 79x145cm Abs.65x85cm

3



Surg.glove latex 8.0 PF 2/1

2



Surg.glove latex 8.5 PF 2/1

1



Skin marker taper tip Violet

1



Reinforced Table Cover 190 x280 wrapping

1



SA Label 1,6 x 5cm Red TEHNOMEDICA SRL

1